

### **REMARKS**

Claims 1-37 were pending in the application. Claims 1-24 and 30-37 have been cancelled without prejudice as being drawn to a non-elected invention. Claims 25 and 28 have been amended. New claims 38-47 have been added. Accordingly, after entry of the instant amendments, claims 25-29 and 38-47 will be pending in the application.

Support for new claims 38-47 can be found in the specification and claims as originally filed. Specific support for new claim 38 can be found in Figure 9B. Specific support for new claims 39 and 40 can be found at page 15, lines 13-15 of the specification (helix-turn-helix) and at page 40, line 15 through page 41, line 6 of the specification (dendrimer). Specific support for new claim 41 can be found at page 38, lines 4-28 of the specification. Specific support for new claim 42 can be found at page 38, lines 18-22 of the specification. Specific support for new claim 43 can be found at page 38, lines 27-28 of the specification (FasL) and at page 77, lines 9-23 of the specification (CD80 and CD86). Specific support for new claims 44 and 46 can be found at page 48, line 4 through page 50, line 28 of the specification. Specific support for new claims 45 and 47 can be found at page 15, lines 21-23 of the specification. Specific support for new claim 48 can be found at page

The specification has been amended to make minor corrections to the abstract and to add the priority information. Applicants submit herewith a "VERSION WITH MARKINGS TO SHOW CHANGES MADE," which shows the amendments made to the claims and the specification. All of the claims, whether or not amended, are presented herein for the Examiner's convenience in APPENDIX A. No new matter has been added by the amendments to the claims or the specification. Applicants reserve the right to pursue the subject matter of the cancelled claims in this or a separate application.

Applicants appreciate the notification that the elected species was found free of the prior art.

**Priority**

The application has been amended to include a specific reference to the prior application in the first sentence of the specification.

**Oath or Declaration**

The oath or declaration was objected to because of non-initialed and/or non-dated alterations thereon. Applicants submit herewith a new declaration executed by the inventors which is in compliance with 37 C.F.R. 1.67(a). Also submitted herewith is a request under 37 C.F.R. 1.48(b) to amend the inventorship, as inventor Jorge Acevedo is no longer an inventor of at least one claim remaining in the application. The new declaration has been executed by the remaining inventors, in accordance with this change.

**Specification**

The abstract has been objected to because it contains the word “novel.” Applicants have amended the abstract to remove the word “novel,” obviating the objection.

**Claim Objections**

Claims 25 and 28 have been objected to because of inconsistency between semicolons and commas. Applicants have amended claims 25 and 28 to replace the semicolons with commas, obviating the rejection.

**Rejection of Claims 25 and 27-28 Under 35 U.S.C. 112, Second Paragraph**

Claims 25 and 27-28 were rejected under 35 U.S.C. 112, second paragraph, because, according to the Examiner, the phrase “molecule the same” is indefinite. Claims 25 and 27 were also rejected under 35 U.S.C. 112, second paragraph, because, according to the Examiner, the phrase “complex comprising an sc-MHC class following general formula” is indefinite.

While Applicants respectfully disagree that any issues of indefiniteness are presented by the original claims, the claims also have been amended to obviate the rejection. For instance, the term “same or different” has been deleted from claims 25 and 28 as that term is merely repetitive of the term “independently”. In view thereof, withdrawal of the rejection is requested.

**Rejection of Claims 25-29 Under 35 U.S.C. 102(e)**

Claims 25-29 were rejected under 35 U.S.C. 102(e) as being anticipated by Hirsch et al. (U.S. Patent 6,211,342). The rejection is respectfully traversed.

Applicants claim *single-chain* MHC class II molecules, where the MHC class II molecule is linked in sequence an MHC  $\beta$  chain-peptide linker-MHC  $\alpha$  chain.

Hirsch et al. does not teach or suggest Applicants’ claimed invention. Hirsch is directed to associated molecules. The examples of Hirsch do not disclose construction of a single chain class II molecule. Other cited disclosure of Hirsch is vague and does not disclose a single chain class II molecule having linked in sequence an MHC  $\beta$  chain-peptide linker-MHC  $\alpha$  chain.

In view thereof, reconsideration and withdrawal of the rejection are requested. See *In re Marshall, supra*. 198 USPQ at 346 (“[r]ejections under 35 USC 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art.”).

**Rejection of Claims 25-29 Under 35 U.S.C. 102(e)**

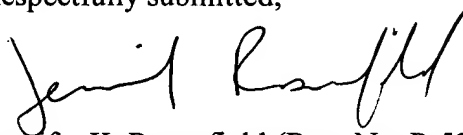
Claims 25-29 were rejected under 35 U.S.C. 102(e) as being anticipated by Rhode et al. (U.S. Patent 5,869,270). The rejection is respectfully traversed.

In order for claims to be rejected under 35 U.S.C. 102(e) as being anticipated by a reference, the reference must be “by another.” In view of the amendment of the inventorship under 37 C.F.R. 1.48(b), the inventive entity of the instant application and the inventive entity of Rhode et al. are the same. Accordingly, Rhode et al. is not available as a 102(e) reference under which to reject the pending claims. Applicants respectfully request reconsideration and withdrawal of the rejection.

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It is believed the application in condition for immediate allowance, which action is earnestly solicited.

Respectfully submitted,



Jennifer K. Rosenfield (Reg. No. P-53,531)  
Agent for Applicants  
EDWARDS & ANGELL, LLP  
*Dike, Bronstein, Roberts & Cushman IP Group*  
P.O. Box 9169  
Boston, MA 02209  
(617) 439-4444

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE SPECIFICATION**

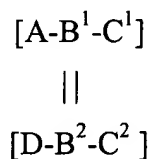
*The abstract has been amended as follows:*

The present invention relates to ~~novel~~ complexes of major ~~histocompatibility~~ histocompatibility complex (MHC) molecules and uses of such complexes. In one aspect, the invention relates to single chain MHC class II complexes that include a class II  $\beta$ 2 chain modification, e.g., deletion of essentially the entire class II  $\beta$ 2 chain. In another aspect, the invention features single chain MHC class II which comprise an immunoglobulin constant chain or fragment. Further provided are polyspecific MHC complexes comprising at least one single chain MHC class II molecule. MHC complexes of the invention are useful for a variety of applications including: 1) in vitro screens for identification and isolation of peptides that modulate activity of selected T cells, including peptides that are T cell receptor antagonists and partial agonists, and 2) methods for suppressing or inducing an immune response in a mammal.

**IN THE CLAIMS**

Claims 25 and 28 have been amended as follows:

25. (Amended) An empty polyspecific MHC complex comprising an sc-MHC class II molecule comprising linked in sequence an MHC  $\beta$  chain-peptide linker-MHC  $\alpha$  chain, the MHC molecule having the following general formula:



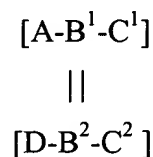
wherein,

- a) A represents at least one empty sc-MHC class II molecule,
- b) B1, B2 are each independently a joining molecule ~~the same or different~~,
- c) C1, C2 are each independently an effector molecule ~~the same or different~~ or -H, ;

and

- d) D represents at least one empty sc-MHC class II molecule, ligand binding molecule or -H.

28. **(Amended)** A polyspecific MHC complex fusion molecule comprising an sc-MHC molecule with peptide binding groove, ~~the MHC molecule comprising linked in sequence an MHC  $\beta$  chain-peptide linker-MHC  $\alpha$  chain~~, the complex being represented by the following formula:



wherein,

- a) A represents at least one empty sc-MHC class II molecule comprising a recombinantly fused presenting peptide,
  - b) B1, B2 are each independently a joining molecule ~~the same or different~~,
  - c) C1, C2 are each independently an effector molecule ~~the same or different~~ or -H, ;
- and
- d) D represents at least one empty sc-MHC class II molecule, ligand binding molecule or -H.